UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

6/28/94

MEMORANDUM

SUBJECT: Transmittal of EFED List D Summary Report for Muscalure Chemical #103201; Case #4112

FROM: Kathy Monk
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

THRU: for Evert K. Byington, Chief
Science Analysis & Coordination Staff,
Environmental Fate and Effects Division

TO: Jay S. Ellenberger, Chief
Accelerated Reregistration Branch,
Special Review & Reregistration Division

Attached please find the following documents for the completed EFED summary report of muscalure.

1. EFGWB Science Chapter
2. EEB Science Chapter
3. SACS Reregistration Summary Report

Three eco-tox data requirements are outstanding, however, a risk assessment has been done using available information. If you have any questions concerning this case, please contact Kathy Monk 305-6120.

CC:\ (with SACS Reregistration Summary Report attached)

Anne Barton
Hank Jacoby
Elizabeth Leovey
List D File
Tony Maciorowski
Doug Urban
Evert Byington
List D Cover Memo File
Laura Dye
Tom Myers
Peter Caulkins

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

6/28/94

MEMORANDUM

SACS RED SUMMARY REPORT

FROM: Kathy Monk
Science Analysis and Coordination Staff

THRU: Evert Byington, Chief
Science Analysis and Coordination Staff

TO: Tom Myers
Special Review and Reregistration Division

Case Number: #4112

Chemical Number: #103201

Active Ingredient: (Z)-9 and E-9-Tricosene

Common Name: Muscalure

List: D

The SACS summary report for the RED for muscalure is attached. Three eco-tox data requirements are outstanding, however, a risk assessment has been done using available information.

Introduction

I. Data Gaps and Value of Information Analysis

Ecological Effects:

The previously imposed requirements which have not been fulfilled are:

71-4 Avian Reproduction
154-8 Freshwater fish acute
154-9 Freshwater invertebrate acute

These studies were previously submitted, but have been classified as supplemental.

Products made from Muscalure are of two types. The first are products that contain Muscalure in bait stations, strips, belts, etc. For these products, for which minimal exposure to non-target organisms is expected, the data submitted are adequate and the above studies would not need to be repeated. The second type of product are crystals and granules spread on the ground. For these products, which involve some exposure in the environment, the tests need to be repeated to confirm the preliminary assessment made using the supplemental data.

Environmental Fate:

No environmental fate data requirements have been imposed. The Agency is relying on data available in the literature to assess the environmental fate of this compound for its current uses.

II. Risk Characterization

The preliminary risk assessment, based on supplementary studies, indicates that there is a potential for avian reproductive effects. The supplemental toxicity tests for aquatic invertebrates indicates that muscalure is highly toxic to aquatic invertebrates, however, exposure is expected to be minimal.

III. Mitigation

To mitigate the risk posed by the crystal and granule products and to eliminate the need to repeat the studies listed in Section I above, it is recommended that these formulations be changed to a solid matrix or impregnated material design. This would eliminate the concern for non-target organisms.

Another concern with the crystal and granule products is that they are formulated with the insecticide methomyl. It is likely that the risk assessments for this active ingredient will show greater concern for this use. Until the RED for methomyl is completed, we

question continuing the use of the crystal and granule formulations and, specifically, their use around picnic areas where birds, as well as children, may be exposed.

Finally the label should be strengthened, for all products, to specify the total number of applications that are allowed; amount of active ingredient per application; minimum number of days between each application; and percent of active ingredients in the formulations.

IV. Labeling

Manufacturing-Use Products

The following label statement is required on all manufacturing-use products:

> This pesticide is highly toxic to freshwater aquatic invertebrates and may impair reproduction in birds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

End-Use Products

Environmental hazard requires the following labeling statement:

> This pesticide is highly toxic to freshwater aquatic invertebrates and may impair reproduction in birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate, and Transport

The Agency is relying on data available in the literature to assess the environmental fate of this compound for its current uses.

b. Environmental Fate Assessment

Muscalure, (cis-9-tricosene), is a twenty-three carbon straight chain compound with a double bond between the ninth and tenth carbon atom. It is in the general hydrocarbon family referred to as alkenes. This family of compounds is relatively more reactive than saturated hydrocarbons (alkanes) in laboratory reactions. However, in the environment alkenes would be expected to persist. The solubility of straight chain alkenes generally tends to decrease as the number of carbons increases. The major routes of dissipation in the environment would be expected to be volatilization and microbial mediated degradation.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Animal Data

In order to establish the toxicity of muscalure to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on either a waterfowl species or an upland game species (preferably the bobwhite quail); and one subacute dietary (LC_{50}) study on one species of waterfowl or one species of upland game bird (preferably the bobwhite quail).

(a) Avian Acute Toxicity

Avian Acute Oral Toxicity Findings			
Species	**% Test Material (TGAI)**	**LD_{50}**	**Conclusions**
Bobwhite quail	>98%	>2000 mg/kg	Practically Non-toxic
Mallard duck	>96%	>4650 mg/kg	Practically Non-toxic
Mallard duck	98.7%	>4640 mg/kg	Practically Non-toxic

These results indicate that muscalure is practically non-toxic to birds on an acute oral basis. The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (ID #'s 41785403; ESC1; 232388)

(b) Avian Subacute Dietary Toxicity

Avian Subacute Dietary Toxicity Findings			
Species	**% Test Material**	**LC_{50}**	**Conclusions**
Bobwhite Quail	>98%	>5000 ppm	Practically Non-toxic
Mallard Duck	98.7%	>10,000 ppm	Practically Non-toxic
Bobwhite Quail	98.7%	>10,000 ppm	Practically Non-toxic
Bobwhite Quail	72.9%	>4640 ppm	Practically Non-toxic
Mallard Duck	72.9%	>4640 ppm	Practically Non-toxic

On a subacute dietary basis, technical Muscalure is practically non-toxic to upland game birds and waterfowl. The guideline requirement for the avian dietary LC_{50} study is fulfilled. (ID #s 41785404; 232388; 232017)

(c) Avian Reproduction

Avian reproduction studies are required for a pesticide when birds may be subjected to repeated or continuous exposure, the pesticide is stable in the environment, the pesticide is stored or accumulated in plant or animal tissues, or if

mammalian reproduction studies indicate reproduction hazard. In this case studies submitted previously indicate reproductive effects at low concentrations. Five studies have been submitted and reviewed, however, each is classified as supplemental.

Avian Reproduction Findings		
Species	**% A.I.**	**Reproductive Impairment**
Mallard Duck	94.7%	>0.10 ppm
Mallard Duck	TGAI	2.0 ppm
Mallard Duck	98.7%	20.0 ppm
Bobwhite Quail	TGAI	>20.0 ppm
Bobwhite Quail	98.7%	>20.0 ppm

For upland game birds there were no reproductive effects up to 20 ppm which was the highest dose tested. For waterfowl adverse reproductive effects were found in two studies. One study indicates effects on normal hatchlings, and 14-day old survivors at 2 ppm and 20 ppm; and on viable embryos and live three-week embryos at 20 ppm. The other study indicates no adverse effects at 2 ppm, however, at 20 ppm there were significant differences from the control for live three-week embryos, normal hatchlings, and 14-day old survivors. These avian reproduction studies were considered supplemental because they do not include all of the necessary data required to complete a risk assessment. (MRID #s 00232017, 00229393, 00232388)

Due to the apparent avian reproductive effects at low levels of exposure a repeated avian reproduction study with the mallard duck is required for products involving the technical material not encased in a solid matrix, in order to determine the reproductive hazard. A repeat study is not required for products used in solid matrix designs, for example, bait traps and stick traps or belts, because it is assumed that this type of product will result in minimal exposure to birds.

(2) Aquatic Animal Data

(a) Freshwater Fish Toxicity

In order to establish the toxicity of Muscalure to freshwater fish, the minimum data required on the technical grade of the active ingredient is one 96-hour acute study. The preferred coldwater species is rainbow trout.

Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	98.7%	> 1000 ppm	Practically Non-toxic
Rainbow trout	72.9%	> 1000 ppm	Practically Non-toxic
Bluegill sunfish	98.7%	> 1000 ppm	Practically Non-toxic
Bluegill sunfish	72.9%	> 1000 ppm	Practically Non-toxic

The data suggest that Muscalure is practically non-toxic to freshwater fish. However, these data were collected in a static test with undissolved test material visible and no analytical data were submitted on actual concentrations in the water. Therefore, the true toxicity of Muscalure to freshwater fish cannot be determined. (MRID #s 232388, 232017)

A repeated study is required for products involving the technical material not encased in a solid matrix, in order to determine the acute toxicity. A repeat study is not required for products used in solid matrix designs, for example bait traps and stick traps or belts, because it is assumed that this type of product will result in minimal exposure of aquatic organisms.

(b) Freshwater Invertebrate Toxicity

In order to establish the toxicity of Muscalure to freshwater invertebrates, the minimum data required on the technical grade of the active ingredient is a 48-hour acute study. The preferable test organism is first instar *Daphnia magna.*

Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Daphnia magna	98.7%	1.08 ppm	Highly toxic

The data suggest that muscalure is highly toxic to freshwater invertebrates. However, these data were collected in a static test with undissolved test material

visible and no analytical data were submitted on actual concentrations in the water. Therefore, the true toxicity of muscalure to freshwater invertebrates cannot be determined. (MRID # 00232388)

A repeated study is required for products involving the technical material not encased in a solid matrix, in order to determine the acute toxicity. A repeat study is not required for products used in solid matrix designs, for example bait traps and stick traps or belts, because it is assumed that this type of product will result in minimal exposure of aquatic organisms.

b. Ecological Effects Risk Assessment

Terrestrial Organisms

For those products which contain solid matrix forms and impregnated materials as the end-use product it is assumed that exposure to terrestrial species will be minimal. The nature of these products and how they are used do not allow for an ecological risk assessment to be performed. However, no adverse effects to terrestrial species are expected with the use of muscalure in these products.

For those products formulated as crystals and granules a risk assessment can be performed with the core acute avian toxicity data and limited use and application information on granular muscalure. From these calculations, minimal acute effects can be expected for the granular formulation for the application rate of 0.25 lb/500 ft^2. However, to calculate the potential effects from the crystalline formulation the density of muscalure is needed.

To estimate the possible chronic effects of the granular and crystalline formulations of muscalure on avian species, a valid chronic study is needed. Tentative results, based on supplemental studies, indicate chronic effects at low levels. To mitigate the risks posed by these products it is recommended that they be changed from crystal and granule formulations to a solid matrix or impregnated material design, such as bait stations and strips.

Aquatic Organisms

For those products which contain solid matrix forms and impregnated materials as the end-use product it is assumed that exposure to aquatic organisms will be minimal. The nature of these products and how they are used do not allow for an ecological risk assessment to be performed. However, no adverse effects to aquatic organisms are expected with the use of muscalure in these products.

For those products formulated as crystals and granules a preliminary aquatic organism risk assessment was performed using the available supplemental acute

freshwater toxicity data and limited use and application information on granular muscalure. A direct application model was used to calculate the expected estimated environmental concentration (EEC) for the granular formulation. Based on this exposure model, the preliminary risk assessment suggests that effects to aquatic invertebrates may occur if accidental direct application occurred. The environmental hazard statement on the label is sufficient to mitigate this risk. However, to confirm this conclusion, the acute freshwater fish and freshwater invertebrate studies need to be repeated.

Endangered Species

For those products formulated as crystals and granules, based on the current use patterns and amount of active ingredient used, potential adverse acute effects to avian and mammalian endangered species would be minimal. However, data on avian reproduction and aquatic fish and invertebrates are needed to determine potential endangered species risk for these endpoints.